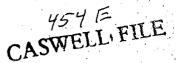
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JAN 12 1990

MEMOR ANDUM

SUBJECT:

GX-071 - 90-DAY DOG STUDY

TO:

MICHAEL MENDEL SON PRODUCT MANAGER (17)

REGISTRATION DIVISION (H75050

FR OM:

LINDA L. TAYLOR, PH.D.

TOXICOLOGY BRANCH II, SECTION II

HEALTH EFFECTS DIVESTON (H7509C)

THR U

K. CLARK SWENTZEL N. Clork Swentzel SECTION II HEAD, TOXICOLOGY BRANCH II

HEALTH EFFECTS DIVISION (H7509C)

MARCIA VAN GEMERT, PH.D. Muan Sener 1/1/90 CHIEF, TOXICOLOGY BRANCH/HFAS/HED (H7509C) GRIFFIN CORPORATION

REGISTRANT:

CHEMICAL:

N-ETHYL PERFLUOROOCTANE SULFONAMID

YNONYMS:

GX-071; SULFLURAMID 0 - 0432

PROJECT: ASWELL NO .:

454E 257188

ECORD NO -:

1812-327

DENTIFYING NO .: ACTION REQUESTED: CONFIRM TELEPHONE CONVERSATION AND REVIEW REVISED

DOG STUDY PROTOCOL.

COMMENT: THE REGISTRANT HAS SUBMITTED THE REVISED (12/07/89) PROTOCOL FOR THE 90-DAY DOG STUDY TO BE PERFORMED ON GX-071. IT IS NOTED THAT DOSE LEVELS HAVE BEEN INCLUDED, WHICH WERE NOT PREVIOUSLY INCLUDED IN THE PROTOCOL (AS DISCUSSED IN THE IT MEMO DATED SEPTEMBER 8, 1989). THE COVER LETTER FROM J.S. LOVELL PROVIDES A COPY OF A LETTER FROM DR. PICCIRILLO TO ME REGARDING THE AGE OF THE DOGS TO BE USED IN THE 90-DAY STUDY. THAT LETTER (UNDATED) FROM DR. PICCIRILLO IS ACCURATE WITH REGARD TO TB II CONCURRENCE WITH THE USE OF THE OLDER DOGS. HOWEVER, MR. LOVELL'S STATEMENT THAT TB II IS IN AGREEMENT WITH THE REVISED PROTOCOL IS NOT ACCRURATE, AS DISCUSSED BELOW.

THE PREVIOUS PROTOCOLS FOR THE 90-DAY DOG STUDY HAVE NOT INDICATED THE DOSE LEVELS THAT ARE TO BE TESTED NOR HAS ANY STATEMENT BEEN MADE THAT ADMINISTRATION BY CAPSULE MAY BE UTILIZED FOLLOWING A PALATIBILITY CHECK OF THE HIGH DOSE. CONCURRENCE FROM THE AGENCY WITH REGARD TO THIS PROPOSED STUDY HAS BEEN ON THE AGE OF THE DOGS AT STUDY INITIATION ONLY, NOT ON DOSE SELECTION. SINCE NO INFORMATION IS PROVIDED IN THE REVISED PROTOCOL AS TO HOW THE DOSES WERE CHOSEN, AND ASSUMING THAT THE STUDY IS CURRENTLY UNDERWAY, NO COMMENT (CONCURRENCE) ON THIS ASPECT IS APPROPRIATE BY TB II AT THIS TIME.